

R E M A R K S

Claims 1-3 and 5-11 are pending and under examination. All of the pending claims stand rejected. The Applicants believe that the amendments and remarks presented herein overcome all of the pending rejections/objections thus placing the application in condition for allowance. Applicants submit herewith, an Information Disclosure Statement for consideration.

I. The Finality Of The Present Office Action Should Be Withdrawn And Cannot Be Reinstated In Response To The Present Request For Continuing Examination

The present Office Action has been made final. Yet the action raises, for the first time, a rejection of the claims in view of Dahlberg et al. Nothing in Applicants' previous amendment necessitated this rejection--i.e., the Examiner's basis for the rejection could equally have applied to the original claims as filed. Specifically, Applicants previous amendments to the claims simply added a "detection" step to link the active step in the method to the preamble and clarified language in view of antecedent basis rejections. The Dahlberg et al. reference could have been raised in the original Office Action. By raising the Dahlberg et al. reference now, Applicants are entitled to a full response and full consideration of the present amendment and response. This basis alone merits withdrawal of the finality and Applicants request that the finality of the Office Action be withdrawn.

A second and independent reason for removal of finality is the Examiner's failure to consider Applicant's previous Amendment and Response. The only rejection retained from the previous Office Action is a 102(e) rejection in view of the '069 patent. In response to this rejection, the Applicants explained that the '069 patent is a priority document of the present case and is not prior art. The Examiner has responded by stating:

"Applicant's arguments have been fully considered but they are not persuasive because the Applicant has failed to point out which elements were not described in the cited '069 Patent."

Applicants' arguments clearly were not fully considered or considered at all. Applicants argued that the cited reference was not prior art. Therefore there is no reason to point out

differences in elements. The Examiner has not acknowledged this position one way or the other (by withdrawing the rejection OR explaining why the cited reference is prior art). Because Applicants' arguments were not considered, the finality of the Office Action must be removed.

II. The Claims Are Definite

The Examiner has rejected claims 1-3 and 5-6 as not having a the preamble directly link to the active steps and claim 5 as lacking proper antecedent basis for the phrase "said." While not agreeing that the claim language is deficient, Applicants have amended the claims in line with the Examiner's suggestions. In particular, claim 1 has been amended to recite that the last active step results in "detecting said target sequence" and the term "said" has been deleted from claim 5. In view of the above, Applicants request that the rejection be withdrawn.

III. Hall et al. Is Not Prior Art

The Examiner has rejected the claims under 102(e) as being anticipated by Hall et al. For the reasons discussed in Section I, above, Applicants believe that Applicants' previous response was not considered. Consideration of this response, copied verbatim below, should result in withdrawal of this rejection.

The Examiner has rejected claims 1-11 as being anticipated under 35 U.S.C. §102(e) by the '069 patent to Hall et al. The Federal Circuit has held "[a] claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single **prior art reference**." *Verdegaal Brothers v. Union Oil Co., of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); emphasis added). The touchstone of anticipation is the Examiner's citation of a reference that actually qualify as being **prior art** over the claims under examination.

The instant application is a continuation-in-part of U.S. 09/381,212 filed September 17, 1999, which is a 35 U.S.C. §371 application of PCT/US98/05809 filed March 24,

1998, which is a PCT application that claims priority to U.S. 08/823,516 filed March 24, 1997, now issued as **U.S. 5,994,069** on November 30, 1999. Applicants thus respectfully submit that the '069 patent is **not prior art** over the pending application--as the present case claims priority to the '069 patent. Therefore, the pending rejection should be withdrawn.

IV. The Claims Are Novel In View Of Dahlberg

The Examiner has rejected claims 1-3 and 5-11 as allegedly being anticipated by Dahlberg. Applicants respectfully disagree. Each of the pending claims requires the element of an "invasive cleavage structure" (either the formation and cleavage of it--claim 1--or materials configured to form an invasive cleavage structure in the presence of a target--claim 7). Dahlberg does not teach or suggest invasive cleavage structures and therefore cannot anticipate the presently claimed invention. The present specification describes invasive cleavage structures, among other places, at the text spanning pages 68-69:

In an invasive cleavage structure, the two oligonucleotides define and hybridize to regions of the target that are adjacent to one another (i.e., regions without any additional region of the target between them). Either or both oligonucleotides may comprise additional portions that are not complementary to the target strand. In addition to hybridizing adjacently, in order to form an invasive cleavage structure, the 3' end of the upstream oligonucleotide must comprise an additional moiety. When both oligonucleotides are hybridized to a target strand to form a structure and such a 3' moiety is present on the upstream oligonucleotide within the structure, the oligonucleotides may be said to overlap, and the structure may be described as an overlapping, or invasive cleavage structure.

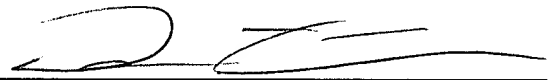
Dahlberg does not teach or suggest any cleavage structures where the upstream oligonucleotide contains a 3' portion or moiety that overlaps with a hybridized region of the downstream oligonucleotide at a position where the upstream and downstream oligonucleotides adjacently hybridize to the target nucleic acid. The Examiner has not indicated that Dahlberg teaches an invasive cleavage structure or where Dahlberg teaches an invasive cleavage structure. Each of the portions of the Dahlberg specification cited by the Examiner (col. 8, lines 20-62; col. 12, lines 13-54; col. 16, lines 34-67; col. 22, lines 18-38; and col. 43, Example 5) fail to teach or suggest invasive cleavage structures. In each of these cases, the 3' portion of the upstream oligonucleotide does not have a portion or moiety that

overlaps with a hybridized region of the downstream oligonucleotide at a position where the upstream and downstream oligonucleotides adjacently hybridize to the target nucleic acid. In view of the above, Applicants request that the rejection be withdrawn.

C O N C L U S I O N

For the reasons set forth above, it is respectfully submitted that Applicants' claims as amended should be passed to allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

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